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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,089	04/23/2004	Craig Jordan	50229-436	7583

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McDemott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,089	JORDAN, CRAIG	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/07 has been entered.

Claims Status

2. Claims 11-89 are pending in the application.

3. The amendment to the claims includes new limitations/subject matter that alter the inventions of the instant claims. Therefore an election/restriction is required between the inventions of the instant claims. Applicant's assertions are moot due to the alteration of the instant claims and restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 11-15,18-21,27-44,70 and 89 are drawn to a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131, classified in class 424, subclass 1.69.

II. Claims 16,17 and 46-48 are drawn to an assay for detecting the presence of hematologic cancer progenitor cell that express CD123, but do not significantly express CD131 in a sample, classified in class 424, subclass 1.65.

III. Claims 22 and 49-57 are drawn to a method for purging hematologic cancer cells that express CD123, but do not significantly express CD131, classified in class 424, subclass 1.65.

IV. Claims 23 and 58-66 are drawn to a method for impairing cancerous progenitor cells which express CD123, but do not significantly express CD131 in a sample, classified in class 424, subclass 1.65.

V. Claims 24-26 and 67-69 are drawn to a method of purging cancerous progenitor cells that express CD123, but does not significantly express CD131 in a patient in need thereof, classified in class 424, subclass 9.2.

VI. Claims 71,75 and 79-88 are drawn to a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 as examined by flow cytometry, classified in class 424, subclass 9.34.

VII. Claims 72 and 76 are drawn to a method for impairing cancerous progenitor cells, which express CD123, but does not significantly express CD131 as examined by flow cytometry, classified in class 424, subclass 9.34.

VIII. Claims 73 and 77 are drawn to a method for purging hematologic cancer progenitor cells that express CD123, but does not significantly express CD131 as examined by flow cytometry, classified in class 424, subclass 1.65.

IX. Claims 74 and 78 are drawn to a method of purging cancerous progenitor cells, which express CD123, but does not significantly express CD131 as examined by flow cytometry, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and VI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). (In regards to inventions I and II): In the instant case, the different inventions are a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and an assay for detecting the presence of hematologic cancer progenitor cell that express CD123, but do not significantly express CD131 in a sample. The invention of group II does not necessarily contain the cytotoxic agents found in group I, such as hormone, steroid, a ribosome inactivating protein and therefore the assay does not necessarily use the composition of the invention of group I.

3. In regards to inventions I/II and VI: In the instant case, the different inventions are a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly

express CD131 as examined by flow cytometry. The composition of the invention of group VI does not necessarily use the antibodies, such as $F(ab')_2$, Fab or Fv and therefore is unrelated to the compositions of group I and II and which contain the antibodies such as $F(ab')_2$, Fab or Fv.

4. Inventions I and III/V/IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). (In regards to inventions I and III): In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for purging hematologic cancer cells that express CD123, but do not significantly express CD131. The method of the invention of group III does not necessarily use a hematologic cancer progenitor cell from myelodysplastic syndrome of group I and therefore the invention of group III is used with another materially different product.

5. In regards to inventions I and V: In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for purging cancerous progenitor cells that express CD123, but do not significantly express CD131 in a patient in need thereof. The method of group V utilizes a composition comprising an antibody but does not include a cytotoxic agent and therefore can be used with a materially different product than that

of the invention of group I which involves a composition comprising an antibody and a cytotoxic agent.

6. In regards to inventions I and IX: In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for purging cancerous progenitor cells that express CD123, but do not significantly express CD131 as examined by flow cytometry. The method of the invention of group IX does not necessarily utilize a composition containing a cytotoxic agent of the invention of group I, such as hormone, steroid, a ribosome inactivating protein and therefore the invention of group IX can be used with another materially different product. Also, the invention of group IX does not necessarily use a hematologic cancer progenitor cell from myelodysplastic syndrome and therefore can be used with a materially different product.

7. Inventions I and IV/VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). (In regards to inventions I and IV): In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for impairing cancerous progenitor cells, which express CD123, but do not significantly express CD131. The invention of group IV does not necessarily use a hematologic

cancer progenitor cell from myelodysplastic syndrome and therefore can be used with a materially different product.

8. In regards to inventions I and VII: In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for impairing cancerous progenitor cells, which express CD123, but do not significantly express CD131 as examined by flow cytometry. The invention of group VII does not necessarily use a hematologic cancer progenitor cell from myelodysplastic syndrome and therefore can be used with a materially different product. Also, the method of the invention of group VII does not necessarily utilize a composition containing a cytotoxic agent of the invention of group I, such as hormone, steroid, a ribosome inactivating protein and therefore the invention of group VII can be used with another materially different product.

9. In regards to inventions I and VIII: In the instant case a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 and a method for purging hematologic cancer progenitor cells that express CD123, but does not significantly express CD131 as examined by flow cytometry. The invention of group VIII does not necessarily use a hematologic cancer progenitor cell from myelodysplastic syndrome and therefore can be used in a materially different process than for using the composition of group I. Also, the method of the invention of group VIII does not necessarily utilize a composition containing a cytotoxic agent of the invention of group I, such as hormone, steroid, a ribosome inactivating

protein and therefore the invention of group VIII can be used with another materially different product

10. Inventions II and III/IV/V/VII/VIII/IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions an assay for detecting the presence of hematologic cancer progenitor cell that express CD123, but do not significantly express CD131 in a sample, a method for purging hematologic cancer cells that express CD123, but do not significantly express CD131 (III), a method for impairing cancerous progenitor cells which express CD123, but do not significantly express CD131 in a sample (IV), a method of purging cancerous progenitor cells that express CD123, but does not significantly express CD131 in a patient in need thereof (V), a method for impairing cancerous progenitor cells, which express CD123, but does not significantly express CD131 as examined by flow cytometry (VII), a method for purging hematologic cancer progenitor cells that express CD123, but does not significantly express CD131 as examined by flow cytometry (VIII) and a method of purging cancerous progenitor cells, which express CD123, but does not significantly express CD131 as examined by flow cytometry (IX). The invention of group II utilized samples, such as urine, saliva, feces, etc. that the methods of the groups II-V and VII-IX do not include.

11. Inventions III and IV/V/VI/VII/VIII/IX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In

the instant case, the different inventions of group IV and III where the invention of group IV does not use hematologic cancer progenitor cells that are used for the invention of group III.

12. In regards to the different inventions of group V and groups III, IV,VI,VII and VIII, the invention of group V does not use hemotologic cancer progenitor cells that are used in the invention of group III and does not use a composition comprising a cytotoxic agent that is included in the composition of the invention of group III and the composition used for the invention of group V does not contain a cytotoxic agent which is included in the compositions of the inventions of groups III, IV,VI,VII and VIII.

13. In regards to the different inventions of group VI and group III/IV, the invention of group VI does not use a composition comprising the antibodies, such as $F(ab')_2$, Fab or Fv which are included in the composition of the invention of the methods of group III and IV.

14. In regards to the different inventions of group VII/VIII and groups III/IV/VI, the inventions of group VII and VIII do not use a composition comprising the antibodies, such as $F(ab')_2$, Fab, Fv or a cytotoxic agent, such as hormone, steroid, a ribosome inactivating protein which are included in the composition of the invention of the method of group III,IV and VI.

15. In regards to the different inventions of group IX and III/IV/VI/VII/VIII, the invention of group IX does not use a composition comprising a cytotoxic agent and/or antibodies, such as $F(ab')_2$, Fab, Fv that are included in the composition of the invention of the method of group III,IV,VI,VII and VIII.

16. In regards to the different inventions of group IX and V, the invention of group IX does not necessarily involve bone marrow and peripheral blood samples of the invention of group V.

17. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

18. Claims 11-89 are generic to the following disclosed patentably distinct species:

19. cytotoxic agent: a.) chemotherapeutic agent, b.) plant-derived, fungus-derived, bacteria-derived toxin, c.) radioisotope (one of alpha or beta radioisotope), d.) cytotoxic agents of claims 38, 44, 55, 63 and 86

20. The species are independent or distinct because the cytotoxic agents have different structures, activities, utilities, preparations, etc. and therefore require different searches. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) **an election of a species and/or invention** to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and/or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

21. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
January 17, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER